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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,362	01/23/2004	Mark William Bodmer	674525-2008	7568

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NEW YORK, NY 10151

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,362

Applicant(s)

BODMER ET AL.

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/23/04; 6/28/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. The following is noted:

Claims 6, 7, 8, 10, 11, 12, 13, 14, and 15 encompass 20 different second sequence wherein the second sequence comprising various proteins, polynucleotide encoding various proteins, antibody that binds to various proteins and various polynucleotide encoding various antibody that binds to various protein wherein the protein modulates a T cell signaling pathway that either upregulates or downregulate Notch activity in the claimed conjugate. Claims 16, 17, 18, 19, 20, 21, 22, 23, and 24 encompass 16 different first sequence comprising various protein, various polynucleotide encoding said various proteins, various antibodies that binds to various protein and polynucleotides encoding various antibodies that binds to various protein expressed on an antigen presenting cell (APC) for the claimed conjugates.

These conjugates as claimed differ with respect to their structure, binding specificity and immune functions (upregulates versus down regulate Notch expression or activity, for example); a person of ordinary skill in the art would not envision one in view of the other. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

II. Claims 1-33 are pending.

Election/Restrictions

III. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Groups 1-320. Claims 6, 17-18, 19-24, and 31, drawn to a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a specific protein** which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific protein conjugate comprising (1) a specific second protein sequence such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (2) a specific first

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protein sequence such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 321-642. Claims 6, 17-18, 25-29, and 31, drawn to a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a polynucleotide encoding a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a polynucleotide coding for a specific protein** which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific polynucleotide conjugate comprising a specific polynucleotide encoding (1) a specific second polynucleotide sequence encoding the protein such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, a specific polynucleotide encoding Notch; (2) a specific first polynucleotide sequence the protein such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 643-960. Claims 9-10, 17-18, and 31, drawn to a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises an antibody** that binds to a specific protein which binds to an presenting cell (APC) and wherein the **second sequence comprises an antibody** which binds to protein which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific conjugate comprising a (1) second sequence wherein the second sequence is an antibody that binds specifically to a protein such as the ones recited in claims 6, 7, 8, 10,

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11, 14, or 15, for example, a specific antibody that binds to Notch, (2) a specific first sequence wherein the first sequence is an antibody that binds specifically to a specific protein such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 961-1280. Claims 9-10, 17-18, 25-29 and 31, drawn to a conjugate comprising a first sequence and a second sequence wherein the **first sequence is a polynucleotide encoding an antibody** which binds to an antigen presenting cell (APC) and a **second sequence is a polynucleotide encoding an antibody** which modulates a T cell signaling pathway and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific polynucleotide encoding a specific antibody that binds to a (1) specific second sequence such as the ones recited in claims 6, 7, 8, 9, 11, 14, or 15, for example, Notch, a specific polynucleotide encoding an antibody that binds to (2) a first sequence such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 1281-1600. Claim 30, drawn to method of **targeting a protein** for Notch signaling modulation to an APC comprising exposing the APC to the conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a specific protein** which modulates a T cell signaling pathway.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of targeting a protein for Notch signaling by exposing to the APC to the specific conjugate comprising (1) a specific second sequence such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (2) a specific first sequence such as the ones

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recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 1601-1920. Claim 30, drawn to method of **targeting a polynucleotide** for Notch signaling modulation to an APC comprising exposing the APC to the conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a polynucleotide encoding a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a polynucleotide coding for a specific protein** which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to method of **targeting a polynucleotide** for Notch signaling using a specific polynucleotide conjugate comprising a specific polynucleotide encoding (1) a specific second sequence such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (2) a specific polynucleotide encoding (2) a specific first sequence such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 1921-2240. Claim 30, drawn to method of **targeting a protein** for Notch signaling modulation to an APC comprising exposing the APC to a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises an antibody** that binds to a specific protein which binds to an presenting cell (APC) and wherein the **second sequence comprises an antibody** which binds to protein which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to method of **targeting a protein** for Notch signaling using a specific antibody conjugate

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comprising an antibody that binds to a (1) specific second sequence such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, a specific antibody that binds to a (2) specific first sequence such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 2241-2560. Claim 30, drawn to method of **targeting a polynucleotide** for Notch signaling modulation to an APC comprising exposing the APC to a conjugate comprising a first sequence and a second sequence wherein the **first sequence is a polynucleotide encoding an antibody** which binds to an antigen presenting cell (APC) and a **second sequence is a polynucleotide encoding an antibody** which modulates a T cell signaling pathway and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a specific method of targeting a polynucleotide for Notch signaling using a specific **polynucleotide encoding an antibody** that binds to a (1) **specific second sequence** such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, a specific polynucleotide encoding an antibody that binds to a (2) **first sequence** such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (3) whether the second sequence upregulates or inhibits Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 2561-2880. Claims 32-33, drawn to method of **preventing or treating a specific disease or infection** in a subject comprising administering to the subject a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a specific protein** which modulates a T cell signaling pathway.

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Note: Applicant is required to elect a single **Group** of invention drawn to a method of preventing or treating (1) **a specific disease or infection** using a specific conjugate comprising (2) **a specific second sequence** such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (3) **a specific first sequence** such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (4) whether the second sequence **upregulates or inhibits** Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 2881-3200. Claims 32-33, drawn to method of **preventing or treating a specific disease or infection** in a subject comprising administering to the subject a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a polynucleotide encoding a specific protein** which binds to an antigen presenting cell (APC) and wherein the **second sequence comprises a polynucleotide coding for a specific protein** which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of preventing or treating (1) **a specific disease or infection** using a specific conjugate comprising a specific polynucleotide encoding (2) **a specific second sequence** such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (3) a specific polynucleotide encoding (3) **a specific first sequence** such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (4) whether the second sequence **upregulates or inhibits** Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 3201-3520. Claims 32-33, drawn to method of **preventing or treating a specific disease or infection** in a subject comprising administering to the subject a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises an antibody** that binds to a specific protein which binds to an presenting cell (APC) and

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wherein the **second sequence comprises an antibody** which binds to protein which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of preventing or treating (1) **a specific disease or infection** using a specific conjugate comprising a specific antibody that binds to (2) **a specific second sequence** such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (3) a specific antibody that binds to (3) **a specific first sequence** such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (4) whether the second sequence **upregulates or inhibits** Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

Groups 3521-3840. Claims 32-33, drawn to method of **preventing or treating a specific disease or infection** in a subject comprising administering to the subject a conjugate comprising a first sequence and a second sequence wherein the **first sequence comprises a polynucleotide encoding an antibody that binds to a specific protein** on antigen presenting cell (APC) and wherein the **second sequence comprises a polynucleotide coding for a specific antibody that binds to a protein** which modulates a T cell signaling pathway, and a composition comprising said conjugate.

Note: Applicant is required to elect a single **Group** of invention drawn to a method of preventing or treating (1) **a specific disease or infection** using a specific conjugate comprising a specific polynucleotide encoding an antibody that binds to (2) **a specific second sequence** such as the ones recited in claims 6, 7, 8, 10, 11, 14, or 15, for example, Notch, (3) a specific polynucleotide encoding an antibody that binds to (3) **a specific first sequence** such as the ones recited in claims 17, for example, MHC class II, or a specific superantigen recited in claims 21, 22, 23, and 24 and (4) whether the second sequence **upregulates or inhibits** Notch signaling such as the ones recited in claims 9 and 12.

Please identify the elected invention by a specific group and the claims that read on the elected group for purposes of examination.

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Linking claims 1-5 will be examined along with Groups 1-1280 if any one of said Groups is elected.

Linking claim 1 will be examined along with Groups 1281-3840 if any one of said Groups is elected.

Claims 1-5 link inventions 1-1280. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-5.

Claim 1 links inventions 1281-3840. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups 1-3840 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The WO 96/01650 publication (PTO 892) teaches a conjugate comprising a first sequence and a second sequence wherein the first sequence comprises a protein such as antibody that binds to MHC class II which inherently expressed on antigen presenting cell (APC) and a second sequence comprises a protein such as V β chain or a peptide such a mutated superantigen that modulates T cell signaling pathway (instant claim 1) (see claims 1, 3-6, page 3, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

- IV. Accordingly, Groups 1-13840 are not so linked as to form a single general inventive concept and restriction is proper.

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V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

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are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.
The IFW official Fax number is (571) 273-8300.

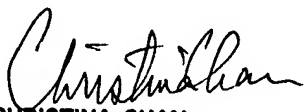
VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

December 23, 2005


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